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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,579	01/28/2002	Saraswati Sukumar	JHU1630-1	7778

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04/21/2003

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EXAMINER

SOUAYA, JEHANNE E

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,579

Applicant(s)

SUKUMAR ET AL.

Examiner

Jehanne E Souaya

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

1. DETAILED ACTION

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-X. Claims 1-41, drawn to methods of determining a predisposition for or diagnosing a cellular proliferative disorder of the breast by detecting the methylation status of patentably distinct nucleic acids, classified in class 435, subclass 6. Wherein each separate group encompasses a single gene. For example, Group I is directed to Twist as well as the primers specific for Twist. Group II is directed to cyclin D2 as well as to primers specific for cyclin D2. Group III is directed to RARB2 as well as the primers specific for RARB2. Group IV is directed to WT1 as well as the primers specific for WT1. Group V is directed to HOXA5 as well as the primers specific for HOXA5. Group VI is directed to 14.3.3 sigma as well as the primers specific for 14.3.3 sigma. Group VII is directed to Estrogen receptor as well as the primers specific for Estrogen receptor. Group VIII is directed to NES-1 as well as the primers specific for NES-1. Group IX is directed to RASSF1A as well as primers specific for RASSF1A. Group X is directed to HIN-1 as well as primers specific for HIN-1. Upon election of one of these groups, applicant is required to specify which primers are specific for the method elected. It is further noted that the claims encompass methods involving a combination of the above

genes. If applicant wishes to elect such, please specify which combination of specific genes for use in the method and the relevant primers.

XI-XX. Claims 42-44, drawn to kits for detecting a cellular proliferative disorder, classified in class 536, subclass 24.3. Group XI is directed to kits comprising primers specific for Twist. Group XII is directed to kits comprising primers specific for cyclin D2. Group XIII is directed to kits comprising primers specific for RARB2. Group XIV is directed to kits comprising primers specific for WT1. Group XV is directed to kits comprising primers specific for HOXA5. Group XVI is directed to kits comprising primers specific for 14.3.3 sigma. Group XVII is directed to kits comprising primers specific for estrogen receptor. Group XVIII is directed to kits comprising primers specific for NES-1. Group XIX is directed to kits comprising primers specific for RASSF1A. Group XX is directed to kits comprising primers specific for HIN-1. It is further noted that the claims encompass kits comprising primers specific for combination of the above genes.

If applicant wishes to elect such, please specify the relevant primers.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions XI-XX and I-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of groups XI-XX can be used to express polypeptides.

The inventions of groups I-X are patentably distinct from each other because each method involves detecting the methylation pattern of patentably distinct genes which are unrelated. Further, the methods of diagnosing cellular proliferation of the breast using each patentably distinct gene are unobvious over one another. The inventions of Groups XI-XX are patentably distinct from each other because they are directed to nucleic acid sequences that hybridize to patentably distinct genes. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-XV, restriction for examination purposes as indicated is proper.
6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Patent examiner
Art Unit 1634

Jehanne Souaya
4/21/03